K010890

APR 1 9 2001

Attachment 4

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

Peter Zurlo
Manager, Regulatory Affairs
BECTON DICKINSON CONSUMER PRODUCTS
1 Becton Drive
Franklin Lakes, NJ 07417-1883
Phone: 201-847-6447
Fax: 201-848-0457

2. **Device Name**: B-D ULTRA-FINE ® II 30g x 3/16" (5mm) Insulin Syringe

3. **Predicate Device**: B-D ULTRA-FINE ® II 30g x 5/16" (8mm)

4. **Device Description:**

The B-D Insulin syringe is designed for the subcutaneous injection of a desired dose of insulin. The syringe has a graduated barrel (in units for U-100 Insulin), a plunger rod and needle/hub assembly. The needle shield is colored orange. The syringe has a 30g x 3/16" (5mm) needle and the scale is marked in ½ unit increments.

This device operates on the principles of a piston syringe. The syringe fluid path is sterile (gamma irradiation sterilization), non-toxic, non-pyrogenic and single use, disposable.

5. **Intended Use**: The B-D insulin syringes are intended for the subcutaneous injection of insulins.

6. **Technological Characteristics**:

The B-D ULTRA-FINE ® II 30g x 3/16" insulin syringe and the predicate device (the B-D ULTRA-FINE ® II 30g X 5/16" insulin syringe) have the identical technological characteristics and perform as piston syringes.

The only difference between the ULTRA-FINE ® II 30g x 3/16" and the predicate device is the injection length of the needle 30g x 3/16" versus the predicate device's 30g x 5/16" needle and the addition of ½ unit scale markings.

Performance Summary:

Bench tests relating to the performance of the needle length were conducted. The tests performed included needle pull-out force, hub pull-off forces, needle angularity, needle break-off testing and dose accuracy.

The results of these tests indicate the new 30 gauge x 3/16" needle performs in a substantially equivalent manner to the predicate device with a 30 gauge x 5/16" needle.

Based on the results of the needle performance testing, B-D Insulin Syringe with the 30 gauge x 3/16" needle is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2001

Mr. Peter Zurlo
Manager of Regulatory Affairs
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, New Jersey 07417-1880

Re: K010890
Trade/Device Name: BD Ultra-Fine II Insulin Syringe-Mini Needle, Model 30G
Regulation Number: 880.5860
Regulatory Class: II
Product Code: FMF
Dated: March 20, 2001
Received: March 26, 2001

Dear Mr. Zurlo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010890

Attachment 2

Indications for Use Statement

510(k) Number (if known)

Device Name BD Ultra Fine II 30g x 3/16" Insulin Syringe

Indications for Use The BD Ultra Fine II 30g x 3/16" Insulin Syringe is intended for the subcutaneous injection of insulins.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

Patricia Cusenza
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010890